

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Oleg Shikhman) Group Art Unit: 3731
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Serial No: 10/726,031) Examiner: Kathleen C. Sonnett
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Filed: December 1, 2003) Confirmation No: 4709
)
For: SUTURE LOADING ASSEMBLY

APPEAL BRIEF

(1) REAL PARTY IN INTEREST

The real party in interest is Interventional Therapies.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(3) STATUS OF CLAIMS

Claims 1-25 are currently pending in the present application. A Final Office Action issued on September 15, 2009, finally rejecting claims 1-25. Applicant appeals from the final rejection of claims 1-25.

(4) STATUS OF AMENDMENTS

The claims have not been amended subsequent to the Final Office Action of September 15, 2009.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

Pursuant to MPEP §1205, a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided with reference to the specification and drawings. It is understood that the reference to the specific embodiments in the specification and drawings is provided for compliance with MPEP §1205 and is not intended to limit the scope of the claims.

Independent claim 1 of the present application claims a suture loading assembly for threading suture material through a surgical instrument that includes, in relevant part, an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument. Claim 1 is recited below, with citations to relevant portions of the Applicant's specification:

1. A suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising (see Applicant's page 2, paragraph [0006], lines 1-3):

a body (see page 16, paragraph [0068], lines 1-5),

an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument (see page 16, paragraph [0070], line 1 – page 17, line 2); and

a flexible loop extending from a distal end of the body, wherein the flexible loop in a first position, is provided through an opening in the body of the surgical instrument, and in a second position is provided at least partially retracted from said opening, wherein in said second position, said suture material is at least partially provided within said surgical instrument opening (see page 17, paragraph [0071], lines 1-21).

Independent claim 11 of the present application claims a suture securing instrument and a suture loading assembly for threading suture material through a surgical instrument that includes, in relevant part, an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument. Claim 11 is recited below, with citations to relevant portions of the Applicant's specification:

11. In combination, a suture securing instrument and a suture loading assembly,

the suture securing instrument comprising (see page 15, paragraph [0067], lines 1-4):

an elongated tubular portion having a distal end and a proximal end, the distal end including a ferrule accepting opening, the proximal end attached to a handle assembly (id);

the suture loading assembly comprising (see page 16, paragraph [0068], lines 1-5):

a body (see page 16, paragraph [0068], lines 1-5),

an attaching member extending from the body for attaching the body on an exterior portion of the elongated tubular portion of the suture securing instrument (see page 16, paragraph [0070], line 1 – page 17, line 2); and,

a flexible loop extending from a distal end of the body, wherein the flexible loop in a first position, is provided through an opening in a ferrule within said ferrule accepting opening, and in a second position is provided at least partially retracted from said ferrule, wherein in said second position, suture material is at least partially provided within said ferrule (see page 17, paragraph [0071], lines 1-21).

Independent claim 21 of the present application claims a method for threading a suture securing instrument, including a suture loading assembly for threading suture material through a surgical instrument that includes, in relevant part, an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument. Claim 21 is recited below, with citations to relevant portions of the Applicant's specification:

21. A method of threading a suture securing instrument comprising:

mounting a suture loading assembly having a body upon a tubular body portion of the suture securing instrument with an attaching member that extends from the body of the suture threading assembly to mount the assembly on an exterior portion of the body of the suturing device (see page 16, paragraph [0068], lines 1-5 and page 16, paragraph [0070], line 1 – page 17, line 2); and,

threading a flexible loop extending from the suture loading assembly through a ferrule within a distal end of the suture loading assembly (see page 17, paragraph [0071], lines 1-21).

Independent claim 25 of the present application claims kit for securing suture material, including a suture loading assembly for threading suture material through a surgical instrument that includes, in relevant part, an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument. Claim 25 is recited below, with citations to relevant portions of the Applicant's specification:

25. A kit for securing suture material within a body of a patient, the kit comprising:

a cutting and crimping device (see page 16, paragraph [0068], lines 1-5);

a ferrule loaded into the cutting and crimping device (see page 16, paragraph [0068], lines 1-5); and,

a suture loading assembly mounted on a tubular portion of the cutting and crimping device (see page 16, paragraph [0070], line 1 – page 17, line 2), a flexible loop extending from the suture loading assembly threaded through the ferrule (see page 17, paragraph [0071], lines 1-21).

(6) **GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The following issues are drawn from the last Final Office Action on the merits dated September 15, 2009:

(A) Claims 1, 2 and 9 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 4,779,616 to Johnson (hereinafter “Johnson”).

(B) Claims 1-5 and 9 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 4,917,082 to Grossi et al. (hereinafter “Grossi”).

(C) Claims 1, 2 and 5-9 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,501,692 to Riza (hereinafter “Riza”).

(D) Claims 1, 9, 11-13 and 20 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,935,149 to Ek (hereinafter “Ek”).

(E) Claims 1, 11-13, 18 and 19 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,520,702 to Sauer et al. (hereinafter “Sauer ‘702”).

(F) Claim 10 has been rejected under 35 USC 103(a) as allegedly being unpatentable over Johnson.

(G) Claims 16 and 17 have been rejected under 35 USC 103(a) as allegedly being unpatentable over Sauer ‘702 in view of U.S. Patent No. 4,102,478 to Samoilov (hereinafter “Samoilov”).

(H) Claims 14, 15 and 21-25 have been rejected under 35 USC 103(a) as allegedly being unpatentable over Sauer '702 in view of U.S. Patent No. 5,643,289 to Sauer (hereinafter "Sauer '289") and U.S. Patent No. 4,134,406 to Iglesias (hereinafter "Iglesias").

(7) **ARGUMENT**

(A) *Claims 1, 2 and 9 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 4,779,616 to Johnson (hereinafter "Johnson").*

In relevant part, independent claim 1 requires "*an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument.*"

Referring to Johnson, item 10 (see FIGURE 1) is simply a suture retrieval device. While it is inserted through a cannula 18 in the body to grab a suture in the body, it does not teach an attaching member at all.

The Examiner would call item 12 an attaching member, but item 12 does not attach (grab in some way) to the device 18. Item 12 is just a handle for loop 14. Also, there is no teaching to attach the handle 12 to cannula 18 (the only disclosed other medical device).

In paragraph 1 of the Examiner's January 8, 2008 action, the Examiner indicates a belief that the handle 12 of Johnson is "capable" of attaching to the exterior portion of a surgical device and could thus read on independent claim 1. Even a cursory review of FIGURE 1 reveals that there is nothing extending from Johnson's item 12 that would be capable of grasping or otherwise attaching to an exterior portion of a separate surgical device.

Further, it is noted that the exterior portion of the surgical device is positively recited in the body of claim 1, and the surgical device is also positively recited in the preamble (Any

terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)). See also *In re Stencil*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar; however, the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

Claim 1 thus positively calls out the suture loading assembly and the surgical device as distinct members, with the attaching member extending from the body of the suture loading assembly to an exterior portion of the surgical device.

In order to make out a prima facie case of obviousness, a proposed combination of prior art references must teach or suggest all of the limitations of the rejected claims. *In re Vaech*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

Because Johnson fails to teach all limitations of independent claim 1, the rejections of claim 1 and dependent claims 2 and 9 are in error.

(B) *Claims 1-5 and 9 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 4,917,082 to Grossi et al. (hereinafter “Grossi”).*

As with Johnson, Grossi fails to teach all of the required limitations of the claims. In relevant part, Grossi requires “a flexible loop extending from a distal end of the body, wherein the flexible loop in a first position, is provided through an opening in the body of the surgical instrument, and in a second position is provided at least partially retracted from said opening, wherein in said second position, said suture material is at least partially provided within said surgical instrument opening.”

It is immediately evident that Grossi does not teach a flexible loop. Grossi teaches an electrode device with a stiff electrode tip 22. Note Grossi, Column 4, lines 59-61, “The second conductor 48, for the cutting loop assembly, is generally comprised of tungsten wire, which is bent at suitable locations to form a portion of two arms 18, 20 and the electrode tip 22 connecting the two arms 18, 20 at the distal tip of the electrode assembly. Also note Column 4, lines 63-65, “Two inner sleeves 50, 52 are placed over the second conductor 48 to add rigidity or stiffness thereto...” Grossi clearly teaches a rigid structure configured to retain shape. Grossi is clearly inapposite to the claimed flexible loop configured to be provided through the distal tip of the surgical device. Because of the rigidity of Grossi, the disclosed Grossi device would not be able to transition between the claimed first position and the second, retracted position.

Because Grossi does not teach all of the required limitations of independent claim 1, the rejection is in error with regard to claims 1-5 and 9.

It is also noted that the Examiner contends the term “suture” does not lend any definition to the claims. However, the practical requirement of the claims by virtue of the suture recitation is that the loop must be flexible such that it can capture the suture. The term clearly supports and lends definable structure to the loop as well as to the recited first and second portions (i.e., the loop threaded through the opening in the surgical device and the loop retracted therethrough with suture captured therein (the rigid, stiffened Grossi would not be able to or be intended to function this way))(Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987) (The claim at issue was directed to a driver for setting a joint of a threaded collar; however, the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. “[T]he framework – the teachings of the prior art – against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited.” *Id.* at 1073, 828 F.2d 754.).

For these additional reasons, the Examiner’s rejections are in error.

(C) *Claims 1, 2 and 5-9 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,501,692 to Riza (hereinafter “Riza”).*

Riza is similar to Johnson as a laparoscopic suture snare. Riza is penetrated into the body, a piston is pushed to extend the snare, and the piston is released to capture/draw in the snare and suture. Riza does not mount onto an exterior portion of a separate device.

In paragraph 1 of the Examiner's January 8, 2008 action, the Examiner treats Riza identically with Johnson. Riza teaches NO more than does Johnson (that is, NOWHERE does Riza teach anything close to an attaching member extending from the Riza device for attaching (or being capable of grabbing or attaching) to a separate device. That teaching or suggestion is simply lacking. Accordingly, the discussion above with regard to Johnson is incorporated herein by reference with regard to Riza.

The rejections with regard to Riza and claims 1-2 and 5-9 are thus in error.

(D) Claims 1, 9, 11-13 and 20 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,935,149 to Elk (hereinafter "Elk").

Elk does describe a suture loading component 400, but fails to teach the "attaching member extending from the body for attaching the body on an exterior portion of the elongated tubular portion of the suture securing instrument." The Elk device is best seen in FIGURE 12. The Examiner claims that the ring 402 attached to the suture loading wire meets the above cited limitation required by independent claims 1 and 11. However, if the body is the attaching wire 400, and the ring 402 is the attaching member, it is clear that the ring 402 in no way extends from the body 400 to the exterior portion of the elongated tubular portion (which would be item 360) for attachment thereto.

Indeed, Elk merely shows the state of the earlier “ripcord” style loader rather than the presently described improvement thereto, which mounts a suture loading assembly body onto the exterior portion of the surgical device. Because Elk fails to teach the above-cited limitations, the rejection is in error.

(E) Claims 1, 11-13, 18 and 19 have been rejected under 35 USC 102(b) as allegedly being anticipated by U.S. Patent No. 5,520,702 to Sauer et al. (hereinafter “Sauer ‘702”).

Sauer ‘702 teaches exactly the same prior art “ripcord” style suture loading as Elk. Accordingly, the discussion above with regard to Elk is incorporated by reference and applied to Sauer ‘702 herein.

Thus, for the same reasons as with Elk above, the rejection is in error. Reconsideration is respectfully requested.

It is also noted that the Examiner first indicated in paragraph 2 of the Examiner’s January 8, 2008 action, that the Applicant’s claim could be met/rendered obvious simply by attaching the ripcord ring of Sauer to the device body by “clipping them together with a third piece.” This is neither taught nor suggested by Sauer ‘702. We again respectfully assert that the Examiner is impermissively using hindsight in an attempt to find the Applicant’s claims using the prior art.

Sauer ‘702 operates by grasping the ring and ‘pulling the ripcord’ from the device. Ignoring (only for the moment) the fact that the Examiner has failed to cite a piece of prior art using such a clip on a ripcord-like ring for attaching the ring to the device body, Sauer would not benefit from such a clip. In the worst case, it would render Sauer ‘702 inoperable (hampering or preventing the ring from being pulled from the device). In the best case, it would be undesirable

(hampering actuation of the clip, or adding an additional undesirable step (in a sterile, medical operation no less) and thus inconveniencing the physician.

There is no motivation to modify Sauer '702. For this additional reason, the Examiner's rejections are in error.

(F) Claim 10 has been rejected under 35 USC 103(a) as allegedly being unpatentable over Johnson.

The deficiencies of Johnson (the fact that Johnson completely fails to teach an attaching member as described by the claims) are detailed above. The above is thus incorporated by reference herein.

(G) Claims 16 and 17 have been rejected under 35 USC 103(a) as allegedly being unpatentable over Sauer '702 in view of Samoilov.

The deficiencies of Sauer '702 have been noted above and are incorporated by reference herein. Samoilov is simply a threader having a handle and similarly completely fails to teach the "attaching member extending from the body for attaching the body on an exterior portion of the elongated tubular portion of the suture securing instrument. Thus, Samoilov does not make up for the deficiencies of Sauer '702, and a *prima facie* case has still not been made out.

(H) Claims 14, 15 and 21-25 have been rejected under 35 USC 103(a) as allegedly being unpatentable over Sauer '702 in view of Sauer '289 and Iglesias.

The deficiencies of Sauer '702 are detailed above and are incorporated herein by reference. Also the discussion above noting the lack of motivation to modify the "ripcord" type device of Sauer '702 (and Sauer '289) is incorporated by reference herein.

Effectively, the Examiner primarily relies on a general teaching (e.g., from Iglesias) that one surgical device may be mounted onto another (Iglesias merely teaches a cutting loop mounted within a channel of a resectoscope). The Examiner then coupled that general teaching with the statement in Sauer '289 that 'the threading tool may be modified so that the threading can be accomplished intracorporeally.' With those two premises, the Examiner concluded that it would be obvious to provide the suture loading body provided as engaged to the body of the separate surgical device.

It is not disputed that some medical devices are a composite of two attached and distinguishable elements. This does not, however, mean that whenever a medical device is engineered to directly engage another (this engineering construction being new in the relevant device art), that it CANNOT be patentable. Indeed, in the present case, going from a 'ripcord' type configuration to a more integrated engaged configuration required engineering and provided great benefits (as noted above, the attaching member of the present ferrule loader permits a more secure grip, eliminates the need for a bulky ring grip and reduces the worry that the distal suture loading ring will slip out). This configuration should not be dismissed SIMPLY on the premise that creating a suture loading body that attaches to the surgical device is obvious simply because other people have combined/attached two objects in the past.

Further, the Examiner calls out the teaching of Sauer '289, (to quote the Examiner): 'the threading tool may be modified so that the threading can be accomplished intracorporeally.' The Examiner indicates that this means construction of a body that attaches to the crimper. However, this does not follow. The most obvious meaning is that the 'ripcord' just extends further through the crimper bore. Thus, Sauer '289 would have the same configuration outside the device (i.e.,

no body attached to the crimping device. To suggest otherwise is to read the applicant's teachings (impermissively using hindsight) into the general comment made by Sauer '289 (which does not mention AT ALL engineering and attaching a suture loader body to the crimping device). Sauer '289 just doesn't provide the motivational link that the Examiner is looking for.

The prior art simply does not teach engineering a suture loader body and attaching it to the surgical device. Similarly, the Examiner cannot say that the engineered combination is obvious because of devices have generally been combined in the past. The present invention is an advancement over the previous suture loaders precisely because a proximal body was engineered to attach to the surgical device rather than relying on a 'rip cord' handle. While claims 21-25 specifically call out a suture securing member having a ferrule through which the suture is loaded, the independent claims each recite the attachment of the suture loader body to the body of the surgical device (and have been amended to specifically clarify that the device is to load suture through an opening in the surgical device).

The simple fact is that both Sauer '702 and Sauer '289 utterly fail to teach a suture loading assembly body attached to the exterior surface of a suturing device (just the 'ripcord' ring attached to the retrieval wire that is threaded through the ferrule). **The Examiner has failed to cite any kind of device with a suture loading assembly body that has an attaching member extending to attach to the exterior of a surgical device.** Just because Iglesias shows one medical device (not even a suturing device) mounted on another (also not a suturing device or related thereto), does not provide the proper motivation to eliminate the ring of Sauer and create a body with attachment portions extending from the body to the device of the suture crimping device.

Again, for these reasons, the rejections are improper and should be withdrawn.

CLAIMS APPENDIX

1. A suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising:

a body,

an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument; and,

a flexible loop extending from a distal end of the body, wherein the flexible loop in a first position, is provided through an opening in the body of the surgical instrument, and in a second position is provided at least partially retracted from said opening, wherein in said second position, said suture material is at least partially provided within said surgical instrument opening.

2. The suture loading assembly of claim 1 wherein the body includes a bore from which the loop extends.

3. The suture loading assembly of claim 1 wherein the attaching member includes two legs extending from the body, an inner portion of each leg curved to accept a cylindrical member of a surgical instrument, wherein the attaching member is slidable along the cylindrical member of the surgical instrument.

4. The suture loading assembly of claim 3 wherein an outer portion of each leg includes an indented area for forming a finger grip.

5. The suture loading assembly of claim 1 further comprising a cap surrounding a portion of the body.

6. The suture loading assembly of claim 5 wherein the cap includes finger grips.

7. The suture loading assembly of claim 6 wherein the finger grips are indents in sides of the cap.

8. The suture loading assembly of claim 5 wherein the cap includes openings for receiving the body and the attaching member.

9. The suture loading assembly of claim 1 wherein the loop is made from wire.

10. The suture loading assembly of claim 9 further comprising a plug inserted within a proximal end of the body for retaining the wire within the body.

11. In combination, a suture securing instrument and a suture loading assembly,

the suture securing instrument comprising:

an elongated tubular portion having a distal end and a proximal end, the distal end including a ferrule accepting opening, the proximal end attached to a handle assembly;

the suture loading assembly comprising:

a body,

an attaching member extending from the body for attaching the body on an exterior portion of the elongated tubular portion of the suture securing instrument; and,

a flexible loop extending from a distal end of the body, wherein the flexible loop in a first position, is provided through an opening in a ferrule within said ferrule accepting opening, and in a second position is provided at least partially retracted from said ferrule, wherein in said second position, suture material is at least partially provided within said ferrule.

12. The combination of claim 11 wherein the loop is threaded through the ferrule accepting opening.

13. The combination of claim 11 wherein the attaching member is slidable along the tubular portion of the suture securing instrument.

14. The combination of claim 13 wherein the attaching member includes two legs extending from the body, an inner portion of each leg curved to accept the tubular portion of the suture securing instrument.

15. The combination of claim 14 wherein an outer portion of each leg includes an indented area for providing a finger grip.

16. The combination of claim 11 wherein the suture loading assembly further comprises a cap surrounding the body and attaching member, the cap extending past the tubular portion.

17. The combination of claim 16 wherein the cap includes a pair of indents usable as finger grips.

18. The combination of claim 11 wherein the suture securing instrument further comprises an aperture in the elongated tubular portion, the aperture located proximally of the ferrule accepting opening, the flexible loop threaded through the aperture prior to threading through the ferrule accepting opening.

19. The combination of claim 18 further comprising a ferrule positioned in the ferrule accepting opening, the flexible loop threaded through the ferrule.

20. The combination of claim 11 wherein the loop is made from a preformed wire bent into a diamond shape.

21. A method of threading a suture securing instrument comprising:

mounting a suture loading assembly having a body upon a tubular body portion of the suture securing instrument with an attaching member that extends from the body of the suture threading assembly to mount the assembly on an exterior portion of the body of the suturing device; and,

threading a flexible loop extending from the suture loading assembly through a ferrule

within a distal end of the suture loading assembly.

22. The method of claim 21 further comprising inserting suture material through the flexible loop.

23. The method of claim 22 further comprising pulling the flexible loop proximally until the suture material is threaded through the ferrule.

24. The method of claim 23 wherein pulling the flexible loop proximally comprises sliding the suture loading assembly proximally along the tubular portion of the suture securing instrument.

25. A kit for securing suture material within a body of a patient, the kit comprising:

a cutting and crimping device;

a ferrule loaded into the cutting and crimping device; and,

a suture loading assembly mounted on a tubular portion of the cutting and crimping device, a flexible loop extending from the suture loading assembly threaded through the ferrule.

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EVIDENCE APPENDIX

None

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RELATED PROCEEDINGS APPENDIX

None

CONCLUSION

The rejections of the claims are in error and should be reversed.

Please charge any fees relating to the filing of this Appeal Brief, including extensions, to Deposit account 06-1130, maintained by the Applicant's attorneys.

Respectfully submitted,
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